U.S. Serial No.: 10/598,223 U.S. Filing Date: August 22, 2006

Response to Office Action Mailed November 12, 2008

Attorney Docket No.: 3124.006A

## REMARKS

Reconsideration and allowance of this application is respectfully requested in view of the amendments above and the remarks below.

Without acquiescing to the proprietary of the rejections in the Office Action dated November 12, 2008, claims 35, 36, 38, 40, 41, 42, 43, 46, 47, 49 and 50 have been amended. New claims 51-54 have been added in this response. Claims 11-34, 37, 44 and 48 have been canceled. Entry of these amendments, reconsideration of the application, allowance of all claims pending herein are respectfully requested in view of the remarks below. Claims 35, 36, 38-43, 45-47,49 and 51-54 are now pending.

## 35 U.S.C. §112 Rejection

In the Office Action, claims 40, 41 and 44 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Specifically, the Office Action reads that the recitation of "such as" when referring to the cartilage replacement material renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. Accordingly, claims 40 and 41 have been amended herein to delete the subject language with new claims 51, 52 and 53 have been added to more distinctly claim the cartilage replacement material.

Further, the Office Action provides that claim 44 was rejected as a repeated claim being an exact replicate of claim 43. Accordingly, claim 44 has been canceled.

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It is respectfully submitted that the §112 rejection is now overcome.

## 35 U.S.C. §103(a) Rejections

In the Office Action, claims 35-38, 43-46 and 48-50 were rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Hayhurst (U.S. Patent No. 5,647,874) in view of Fallin et al. (U.S. Patent No. 6,972,027), claims 39-41 were rejected as being allegedly unpatentable over Hayhurst, in view of Fallin et al. and in further view of Binette (U.S. Publication No. 2005/0113937); and claims 42 and 47 were rejected as being allegedly unpatentable over Hayhurst in view of Fallin et al. in further view of Wolf et al. (U.S. Publication No. 2004/0267314).

Claim 35 has been amended to more particularly point out and distinctly claim the subject invention. Amended claim 35, recites, *inter alia*, a surgical device that includes a section of cartilage replacement material and an anchor that is shaped to sit within tissue at a defect site. The surgical device also includes a flexible member that is attached to the cartilage replacement material and traverse through the section multiple times. The flexible member is further configured to pass through the anchor at least twice.

Specifically, claim 35 has been amended to more distinctly recite Applicant's invention as generally including "at least two pulley mechanisms and a lockable sliding device." Support for the amendment is found at FIGS. 44 and 45 of the application. The addition of new matter has been carefully avoided.

It is asserted in the Office Action that Hayhurst discloses a section of cartilage replacement material 98 (FIG. 17), a flexible member 118 (FIG. 19), an anchor 110 (FIG. 19) connected to an end of the flexible member with the anchor shaped to sit in tissue at the defect site for retention purposes. Further, it is asserted that Hayhurst

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discloses that the flexible member traverses through the section of cartilage replacement material multiple times (Column 10, lines 18-21) with the flexible member being attached to the cartilage replacement material at an attachment point 68 (FIG. 17).

The Office Action also states that Fallin et al. teaches an anchor 56 (FIG. 7) with a flexible member 60 (FIG. 7) that is threaded through the anchor at least twice to form at least two loops (FIG. 7). The first loop is between passageway 68A (FIG. 7) and ends in passageway 68B (FIG. 7). The second loop is between passageways 68B and 68C. It is alleged in the Office Action that the opposite end 89 (FIG. 7) of flexible member is looped around the flexible member 60 to form a sliding device 88 (FIG. 7) for adjusting a distance between an attachment point 58 (FIG. 7) and the anchor. With the sliding device being a slip knot with knot 88 being made loose by pulling at one of its ends by line 95/97 (FIG. 7). The Office Action provides it would have been obvious for one skilled in the art to include two loops and the knots taught by Fallin et al. for the purpose of creating loops and knots to allow slack in the flexible member for easy placement of the anchors as well as a mechanism to retract the slack in order to sufficiently close tears for healing purposes.

It is respectfully submitted that the rejection of claim 35 pursuant to §103(a) is inappropriate and should be withdrawn for the following reasons. It is critical to point out that despite the assertions in the Office Action, there is no disclosure, teaching, suggestion or discussion in Hayhurst as to an attachment point on the cartilage replacement material. The Office Action states that Hayhurst has an attachment point 68 (FIG. 17). In reviewing FIG. 17 and the disclosure provided at Column 7, lines 49-67 and Column 8, lines 1-16, it is found that element 68 actually is a retainer device having a pair of parallel surfaces with slits. The retainer 68 is preferably circular in shape and is moveable along a suture. The retainer 68 is used to maintain the tension in a suture and hold a piece of torn tissue against a stable piece of tissue.

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Retainer 68 is not positioned on the tissue where the suture is integrally connected to that tissue.

In contrast, Applicant's attachment point is a specific insertion location on the section of cartilage replacement material where the flexible member is directly coupled. The attachment point is not moveable or is comprised of a circular body having parallel surfaces with slits. Further, the attachment point does not function to maintain tension in a single suture to hold two pieces of tissue together. Therefore, Hayhurst does not include the necessary attachment point element as disclosed in Applicant's application.

Further, despite the assertions in the Office Action to the contrary, there is no disclosure in Fallin et al. as to at least two pulley mechanisms or a lockable sliding device. Essentially, Fallin et al. discloses a single suture anchor delivery system comprised of a proximal and distal anchor with a lone continuous suture that connects the two stationary anchors. This single suture is attached to each respective anchor by being woven through a series of parallel holes located along each anchor's long axis. One end of the single suture is secured to distal anchor, with the second free end of the suture being positioned adjacent to the proximal anchor. The portion of suture that extends between the stationary distal and proximal anchors may be tensed and loosed by either pulling on a single loop that is created by having slack in the suture between two adjacent holes within the body of the proximal anchor or by pulling on the second free end of the suture. The portion of the suture that extends between the stationary distal and proximal anchors is generally used to sew closed a gap between two sides of a cartilage tear. In no manner does Fallin et al. disclose any type of pulley mechanism that may be used to move a piece of tissue into a defect site.

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The Office Action states further the position that Fallin et al. discloses a sliding device that is a slipknot. A slipknot as defined the *Merriam-Webster Dictionary* is "a knot that slips along a rope or line around which it is made." In looking at figure 7 as referred to in the Office Action, item 88 is only a loop in the suture with no corresponding knot. Passing through loop 88 is a second separate insertion line 94 that is used to enlarge loop 88 (see Column 8, lines 38-40). No knot is seen in any of the figures or is discussed with reference to loop 88. In fact, Fallin et al. is devoid of any disclosure as to a sliding device or slipknot.

Fallin et al. fails to disclose, teach, or suggest two elements missing from the primary reference Hayhurst. In fact, any reference of any sort as to at least two pulley mechanisms or a lockable sliding device is absent from Fallin et al. It is respectfully submitted that neither Hayhurst or Fallin et al. recognizes or solves the same problem as that being solved by Applicant's invention. Specifically, Applicant's invention solves the problem of moving and securing a replacement section of cartilage replacement material within a defect site, wherein the Fallin et al. invention is an apparatus to sew a tear closed by using two stationary serial anchors and Hayhurst discloses only a suture anchor that is used to hold two pieces of tissue together.

Thus, because all of the features (e.g., attachment point, at least two pulley mechanisms and a lockable sliding device) alleged to be disclosed by Hayhurst and Fallin et al. are clearly not disclosed therein, the proposed combination can not make obvious claim 35 of the present application. Withdrawal of the §103(a) rejection is respectfully requested.

Further to this point, Fallin et al. actually teaches away from using a single suture as a pulley mechanism because of the fact that the two anchors described in this reference are positioned in series and at a fixed distance from each other with

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the distal anchor having fixed one end of the suture and the proximal anchor allowing for the tightening of the intermediate portion of the suture to enable the operator to sew closed an opening in a piece of tissue. The disclosed arrangement in Fallin et al. of the connecting suture with the two fixed positions of the anchors actually teaches away from the required movement of the flexible member when configured as at least two pulley mechanisms that are used to move and secure a section of cartilage replacement material into a defect site as claimed by Applicant's invention. Movement of either the proximal or distal anchors by the lone suture in Fallin et al. would result in the failure of the sewing function of the suture that passes between the these two stationary anchors. Thus, combining the cited references of Hayhurst and Fallin et al. would not result in the Applicant's invention and therefore would not achieve the intended purpose of Applicant's invention of moving and securing a cartilage replacement material into a specific defect site.

Accordingly, it is respectfully submitted that independent claim 35 is patentable over the combination of Hayhurst and Fallin et al. Dependent claims 36, 38, 39, 40, 41, 42, 43 and 45 are believed to be allowable for the same reasons noted above in connection with independent claim 35 from which they directly or ultimately depend, as well as for their own additional features. Further, new dependent claims 51, 52, 53 and 54 are also believed to be allowable for the same reasons as noted with claim 35.

With regards to independent claim 46, claim 46 has been amended to more particularly point out and distinctly claim Applicant's invention. Claim 46 recites, *inter alia*, a surgical device having at least one anchor to retain a section of cartilage replacement material in a defect site and a flexible material that has a first end attached to the section of cartilage replacement material with the second end being threaded through the anchor at least twice to form at least two pulley mechanisms and further being looped around a proximal portion of the flexible member to form a

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stopping device. Distal movement of the stopping device along the proximal portion results in the section of cartilage replacement material being positioned and secured within the defect site.

The Office Action states that Hayhurst disclosed all elements of claim 46, specifically at least one anchor 110 (FIG. 19) and a flexible member 118 (FIG. 19) having first and second ends 120 (FIG. 19), with the first end 120 being attachable to the section of cartilage replacement material at an attachment site 68 (FIG. 17).

The Office Action provides further that Fallin et al. teaches a second end of the flexible member threaded through an anchor at least twice to form at least two loops (see FIG. 7), and looped around the flexible member to form a sliding device 88 (FIG. 7). The Office Action states that it would be obvious to one of ordinary skill in the art at the time of the invention to include two loops as taught by Fallin et al., for the purpose of creating loops that allow slack in the flexible member for easy placement of anchors as well as a mechanism to retract the slack in order to sufficiently tightly close tears to ensure proper healing.

As seen in FIG. 17 of the primary applied reference, Hayhurst is an anchor member having an embedded suture proximate to the anchor's midpoint with the suture extending from the anchor to pass through and hold tissue to a bone by using a moveable retainer device that compresses the tissue against the adjacent bone. The retainer device is slideable along the suture in one direction to ensure positioning of the tissue adjacent to the bone. (See Column 3, lines 7-15.)

It is respectfully submitted that the rejection of claim 46 pursuant to §103(c) is inappropriate and should be withdrawn. Specifically as already noted above, Hayhurst does not disclose Applicant's inventive element of a first end of a flexible member being attachable to the section of cartilage replacement material at an

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attachment point. In contrast, Hayhurst describes how a suture that is embedded in an anchor device which is passed or strung through a moveable retainer device that has been positioned along the suture to hold two tissues in close approximation to each other for healing purposes. It is respectfully submitted that the Office Action mischaracterizes the disclosure in Hayhurst in that the reference is devoid of any disclosure wherein an end of a flexible member is directly and permanently fixed at an attachment point for the purposes of moving that section of cartilage replacement material into a defect site. Hayhurst does not describe in any manner such an attachment point.

The Office Action improperly alleges that Hayhurst discloses an attachment point by reference to element 68 (FIG. 17). As already discussed herein, element 68 is actually a moveable retainer disc that slides along a suture and functions to apply a compressive force to hold two pieces of tissue together that have been positioned along a suture. Clearly, a moveable disc used to hold two pieces of tissue together is not an attachment point of an end of a flexible member, wherein the attachment point is a location on a section of cartilage replacement material at which the flexible member is permanently coupled.

In addition, as already discussed above, Fallin et al. does not disclose a flexible member being configured to include at least two pulley mechanisms with a second end of the flexible member being looped around a proximal portion of the flexible member to form a stopping device. Fallin et al. does disclose two stationary anchors positioned in series with one another and connected by a single suture that passes through and engages several openings in each anchor. Fallin et al. is devoid of any teaching, suggestion or motivation to use the single suture as either a pulley mechanism or as a stopping device.

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In fact, Fallin et al. actually teaches away from using a single suture as a pulley mechanism or stopping device because the two anchors are positioned to be in series and at a fixed distance from each other with the distal anchor having fixed one end of the suture and the proximal anchor allowing for the tightening of the intermediate portion of the suture to enable the operator to sew closed an opening in a piece of tissue. The disclosed arrangement in Fallin et al. of the connecting suture with the fixed positions of the anchors teaches away from the required movement of the flexible member when configured as at least two pulley mechanisms that are used to position a section of cartilage replacement material into a defect site as claimed by Applicant's invention. Movement of either the proximal or distal anchors by the suture in Fallin et al. would result in the failure of the sewing function of the suture that passes between the stationary anchors.

Thus, it is again respectfully submitted that all features (e.g., attachment point, first and attached to section of cartilage replacement material, at least two pulley mechanisms and a second end looped around proximal portion to form a stopping device) alleged to be disclosed by Hayhurst in combination with Fallin et al. are not disclosed therein. Therefore, the proposed combination of these references cannot make obvious claim 46 of the present invention and withdrawal of the §103(a) rejection is respectfully requested.

Accordingly, it is respectfully submitted that independent claim 46 is patentable over the combination of Hayhurst and Fallin et al. Dependent claims 47 and 49 are believed to be allowable for the same reasons noted above in connection with claim 46 from which they directly or ultimately depend, as well as for their own additional features.

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## **CONCLUSION**

It is believed that the application is in condition for allowance, and such action is respectfully requested.

If a telephone conference would be of assistance in advancing the prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided.

Respectfully submitted,

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Dated: March 11, 2009

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